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| 10/766,642 | 01/28/2004 | Anthony Atala | 105447-2 | 4621 |
| 21125 7590 11/16/2011 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | EXAMINER FORD, ALLISON M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

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NOV 16 2011

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In re Application of :
Atala :
Serial No.:10/766,642 : Decision on Petition
Filed: 28 January 2004 :
Attorney Docket No.: 105447-2 :

This letter is in response to the petition under 37 CFR 1.144 filed 30 December 2010 requesting reconsideration of the final rejection maintained in the Advisory Action mailed 15 July 2010.

BACKGROUND

On 27 January 2005, in a first Office action on the merits, the examiner divided claims 1-32 into two groups and confirmed that applicants had provisionally elected Group I, claims 1-13 and 23-29, with traverse. No election of species was required. Claims 1-13 and 23-29 were then examined on the merits. Independent claim 1 was directed to a method of organ augmentation comprising the steps of transfecting a population of cells with a plasmid encoding an angiogenesis modulating agent and implanting the transfected cells into a target tissue area. Dependent claims 4 and 7 were directed to transfecting populations of vascular endothelial cells (EC).

On 4 January 2010, following several rounds of prosecution with no further restriction or election of species requirement, applicants amended claim 7 to recite population of endothelial progenitor cells. Newly added claims 38, 39 and 42 also recited endothelial progenitor cells. Applicants also broadened claims 1 and 23 by removing the step of "encapsulating the transfected first population of cells."

On 30 March 2010, in the final Office action, the examiner withdrew claims 7, 38, 39 and 42 as being drawn to non-elected subject matter since "the populations of vascular endothelial cells and myoblasts have been constructively elected by original presentation for prosecution on the

merits.” The examiner then rejected claims 1-4, 6, 12, 23, 25, 26, 28, 40, 41 and 43 under the new grounds as being obvious over Badylak (US 2003/0216811) in light of Badylak (1999) and Penn (US 2004/0161412). An additional rejection was made under 35 U.S.C. 103(a) relying upon the Badylak references in combination with Stewart (US 2006/0251630).

On 30 June 2010, applicants requested reconsideration of withdrawn claims 7, 38, 39 and 42 and reconsideration of the finality.

On 15 July 2010, the examiner mailed an advisory action which maintained the examiner’s treatment of the withdrawn claims and the new grounds of rejection, reasoning that the new rejections were necessitated by applicant’s amendment.

On 16 August 2010, applicants filed a petition under 37 CFR 1.181 for reconsideration of the restriction requirement withdrawing claims 7, 38, 39 and 42 from examination, which was then dismissed as untimely.

On 30 December 2010, applicants filed this petition under 37 CFR 1.144 for reconsideration of the final Office action, along with a request for continued examination.

DISCUSSION

The application, file history and petition have been considered carefully.

The petition filed 9 November 2011 concerns the finality of the Office action mailed 30 March 2010. While applicants agree that the amendment filed 4 January 2010 broadens claims 1 and 23 by deleting the step “encapsulating the transfected first population of cells,” the petition argues that this limitation is not at issue in and could not have prompted the new grounds of rejection. A review of the final rejection shows that the Badylak reference was newly relied upon in order to teach the limitations concerning the polymeric matrix material. This limitation was present in claim 1 as originally filed and had not altered by amendment. The newly made rejection was not set forth to address by whether or not the first transfected populations of cells were encapsulated (the limitation removed by the 4 January 2010 amendment). For this reason, the amendment did not prompt new grounds of rejection and the finality was premature.

Next, it is noted that a petition filed under 37 CFR 1.181 (dismissed as untimely on 9 November 2010) had requested examination of claims 7, 38, 39 and 42 which are drawn to progenitor endothelial cells. The petition provided reasoning that because the method of using vascular endothelial cells in general had already been examined on the merits, claims reciting a method of using a subset of vascular endothelial cells (progenitor endothelial cells) should also be examined on the merits. In support of their position that the progenitor endothelial cells are a type of vascular endothelial cells, the petition pointed to paragraph [0120] of the specification which lists out various types of vascular endothelial cells, including progenitor endothelial cells.

This is persuasive and in keeping with the final sentence of MEP 821.03, which indicates that withdraw of claims by original presentation is only when a restriction could have been properly made between the examined claims and the withdrawn claims. In this instance, the examiner has

set forth a restriction between the genus of all vascular endothelial cells and the subset of those cells which are progenitor endothelial cells. Because the Office cannot restrict between a genus and a species, this requirement cannot be maintained.

DECISION

The petition under 37 CFR 1.144 filed 30 December 2010 for reconsideration of the final Office action is **GRANTED**.

The final Office action mailed 30 March 2010 is withdrawn.

The withdrawal of Claims 7, 38, 39 and 42 by election by original presentation is unwarranted.

Claims 7, 38, 39 and 42 will be examined on the merits along with other already-examined claims.

The application will be returned to the examiner for consideration of the papers filed 30 December 2010 and for preparation of an Office action consistent with this decision.

Should there be any questions regarding this decision, please contact Quality Assurance Specialist Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-0512 or by Official Fax at 571-273-8300.

A handwritten signature in cursive script, reading "George C. Elliott".

George Elliott
Director, Technology Center 1600